

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/16762

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : C12Q 1/02, 1/68, G01N 33/53, 33/566; C07K 1/00; C07H 21/04

US CL : 435-4, 6, 7.21, 7.24, 975; 436/506, 513, 811; 530/350; 536/23.5

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435-4, 6, 7.21, 7.24, 975; 436/506, 513, 811; 530/350; 536/23.5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A --- Y	WU, J. et al. A novel polymorphism of Fc. gamma.RIIla (CD16) alters receptor function and predisposes to autoimmune disease. J. Clin. Invest. September 1997, Vol. 100, No. 5, pages 1059-1070, see entire document.	1-30 ----- 31-35
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☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents.	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is intended to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

28 OCTOBER 1999

Date of mailing of the international search report

09 NOV 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

F. PIERRE VANDERVEGT CV

Telephone No. (703) 308-0196

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/16762

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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PCT/US99/16762

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

WEST 1.2, DIALOG medicine index:

FcR, receptor, IgA, immunoglobulin, alpha, autoimmun?, vasculitis, gingivitis

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 28 JUN 2000

WIPO

PCT

Applicant's or agent's file reference UAB-14252/22	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/16762	International filing date (day/month/year) 23 JULY 1999	Priority date (day/month/year) 24 JULY 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant UAB RESEARCH FOUNDATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

I ☒ Basis of the report

II ☐ Priority

III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

IV ☐ Lack of unity of invention

V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

VI ☐ Certain documents cited

VII ☐ Certain defects in the international application

VIII ☐ Certain observations on the international application

Date of submission of the demand 22 FEBRUARY 2000	Date of completion of this report 11 MAY 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer F. PIERRE VANDER PEST <i>James R. Matthews</i>
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/16762

I. Basis of the report1. With regard to the **elements** of the international application:*☒ the international application as originally filed☒ the description:pages 1-73, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the claims:pages 74-79, as originally filedpages NONE, as amended (together with any statement) under Article 19pages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the drawings:pages 1-5, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the sequence listing part of the description:pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☒ the description, pages 74-77☒ the claims, Nos. NONE☒ the drawings, sheets/~~fig~~ NONE5. ☒ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

Novelty (N)

Claims 1-35 YESClaims NONE NO

Inventive Step (IS)

Claims 1-35 YESClaims NONE NO

Industrial Applicability (IA)

Claims 1-35 YESClaims NONE NO**2. citations and explanations (Rule 70.7)**

Claims 1-35 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method determine the susceptibility of a cell to a disease by determining the Fc.alpha.RI genotype of the cell and measuring the ability of the cell to bind IgA. The claimed method has industrial applicability for determination of susceptibility to a condition associated with altered IgA binding.

The prior art references cited represent the state of the art regarding the determination of polymorphisms of the Fc.alpha.R, but none of the references are found to teach or fairly suggest the instantly claimed method.

----- NEW CITATIONS -----

NONE

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): C12Q 1/02, 1/68, G01N 33/53, 33/566; C07K 1/00; C07H 21/04 and US Cl.: 435/4, 6, 7.21, 7.24, 975; 436/506, 513, 811; 530/350; 536/23.5

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:

NONE

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: ELLEN S. COGEN
GIFFORD, KRASS, GROH, SPRINKLE,
ANDERSON & CITKOWSKI, P.C.
280 N. OLD WOODWARD AVENUE, SUITE 400
BIRMINGHAM, MI 48009

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Applicant's or agent's file reference UAB-14252/22		Date of Mailing <i>(day/month/year)</i> <div style="font-size: 1.2em; font-weight: bold;">26 JUN 2000</div>
IMPORTANT NOTIFICATION		
International application No. PCT/US99/16762	International filing date <i>(day/month/year)</i> 23 JULY 1999	Priority Date <i>(day/month/year)</i> 24 JULY 1998
Applicant UAB RESEARCH FOUNDATION		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer F. Pierre VanderVort <div style="text-align: right; font-family: cursive;">James R. Matthews</div> Telephone No. (703) 308-0196
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Form PCT/IPEA/416 (July 1992)★

GIFFORD, KRASS, GROH, SPRINKLE,
ANDERSON & CITKOWSKI, P.C.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/16762

A. CLASSIFICATION OF SUBJECT MATTER

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US CL : 435-4, 6, 7.21, 7.24, 975; 436/506, 513, 811; 530/350; 536/23.5
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435-4, 6, 7.21, 7.24, 975; 436/506, 513, 811; 530/350; 536/23.5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is intended to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 28 OCTOBER 1999	Date of mailing of the international search report 09 NOV 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer: <i>Pierre Van Der Vegt</i> F. PIERRE VAN DER VEGT CV Telephone No. (703) 308-0196

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/16762

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference UAB-14252/22	<div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> FOR FURTHER ACTION </div> <div> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. </div> </div>	
International application No. PCT/US99/16762	International filing date <i>(day/month/year)</i> 23 JULY 1999	(Earliest) Priority Date <i>(day/month/year)</i> 24 JULY 1998
Applicant UAB RESEARCH FOUNDATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found **unsearchable** (See Box I).

2. ☐ **Unity of invention is lacking** (See Box II).

3. ☐ The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing

☐ filed with the international application.
☐ furnished by the applicant separately from the international application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

☐ transcribed by this Authority.

4. With regard to the title,

☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is:
 Figure No. _____

☐ as suggested by the applicant.
☐ because the applicant failed to suggest a figure.
☐ because this figure better characterizes the invention.

☒ None of the figures.

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FcR, receptor, IgA, immunoglobulin, alpha, autoimmun?, vasculitis, gingivitis

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference UAB-14252/22	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
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Applicant UAB RESEARCH FOUNDATION		

<ol style="list-style-type: none"> 1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>4</u> sheets. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u>0</u> sheets. 	
3. This report contains indications relating to the following items: <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step or industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 	

Date of submission of the demand 22 FEBRUARY 2000	Date of completion of this report 11 MAY 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer F. PIERRE VANDERBEEK <i>James R. Matthews</i>
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/16762

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)

Claims 1-35 YESClaims NONE NO

Inventive Step (IS)

Claims 1-35 YESClaims NONE NO

Industrial Applicability (IA)

Claims 1-35 YESClaims NONE NO

2. citations and explanations (Rule 70.7)

Claims 1-35 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method determine the susceptibility of a cell to a disease by determining the Fc.alpha.RI genotype of the cell and measuring the ability of the cell to bind IgA. The claimed method has industrial applicability for determination of susceptibility to a condition associated with altered IgA binding.

The prior art references cited represent the state of the art regarding the determination of polymorphisms of the Fc.alpha.R, but none of the references are found to teach or fairly suggest the instantly claimed method.

----- NEW CITATIONS -----
NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/16762

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

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I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:

NONE